

Remarks

Claims 1, 3-5 and 8-10 are pending in the application, with claim 1 being the independent claim. Claims 2, 6 and 7 were cancelled. Claims 3-5 and 8 are withdrawn from consideration by the Examiner.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

I. Rejoinder

Upon allowance of elected composition claims (claims 1, 9 and 10) in Group I, Applicants respectfully request rejoinder of method claims (claims 3 and 4) in Group II and process of making claim (claim 8) in Group IV to the elected invention.

II. Rejection under 35 U.S.C. § 112, First Paragraph

The Examiner maintained the rejection to Claims 1, 9 and 10 under 35 U.S.C. § 112, first paragraph, as allegedly for failing to comply with the written description requirement. The Examiner asserts that "[t]he limitation of 'consisting essentially of' was not disclosed in the specification as originally filed or the claims and is therefore 'new matter'." (Office Action mailed August 31, 2009, page 3.) Applicants respectfully traverse the rejection.

Present claims 1, 9 and 10 contain the transitional phrase "consists essentially of," which "limits the scope of a claim to the specified materials or steps 'and those that do

not *materially* affect the *basic* and *novel* characteristic(s)' of the claimed invention." (MPEP 2111.03, citing *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976)) (emphasis in original). This is a well-known phrase in patent parlance. Thus, each of present claims 1, 9 and 10 is directed to a synergistic fungicidal composition contains fluoxastrobin, prothioconazole and tebuconazole as well as additional ingredients, for example extenders and/or surfactants, which do not materially affect the synergistic fungicidal properties of the claimed compositions.

When a specification describes a claimed invention in a manner that conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed, the written description requirement is satisfied. (See MPEP 2163.02, citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)). "Possession may be shown in a variety of ways including description of an actual reduction to practice." "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." (MPEP 2163.02). "To comply with the written description requirement. . . , each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure." (MPEP 2163).

Applicants assert that there exists more than adequate basis in the description to support the phrase "consisting essentially of" in the claims. Applicants direct the Examiner to page 1, line 16 of PCT/EP2004/008040 from which the present application claims priority under 35 U.S.C. § 371. There, the introductory phrase "Es wurde nun gefunden, dass die neue Wirkstoffkombination **aus**" is literally translated to "[i]t has

now been found that the novel active compound combination *out of*." The word "aus" could have been translated to the inclusive language "out of" the recited components, a restrictive statement.

Claim 1 of PCT/EP2004/008040 recites "[w]irkstoffkombination, *enthaltend* eine Verbindung der Formel (I)." This phrase is literally translated to "[a]n active compound combination, *comprising* a compound of the formula (I)."

In sum, in the introductory phrase of Claim 1 of PCT/EP2004/008040 the word "enthaltend" is literally translated to "comprising" in English. Equivalents to the word "aus" on page 1, line 16 are "containing" or "having." Therefore, interpreting the specification as a whole, there is support for the English phrase "consisting essentially of."

Moreover, even though the specification or the claims as originally filed did not use the phrase "consisting essentially of" literally in describing the claimed invention, one of ordinary skill in the art would reasonably conclude that Applicants were in possession of the invention as now claimed at the time of filing at least because Applicants described an exemplary composition containing three active compounds fluoxastrobin, prothioconazole and tebuconazole. The exemplary composition also contains N,N-dimethylacetamide (solvent) and alkylaryl polyglycol ether (emulsifier), which do not materially affect the synergistic fungicidal properties of the composition. (See specification, Example at pages 8 and 9.) As such, possession is shown by description of an actual reduction to practice of the claimed invention. Thus the

transitional phrase "consists essentially of" recited in present claims 1, 9 and 10 is at least implicitly or inherently supported in the originally filed disclosure.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

III. Rejection under 35 U.S.C. § 112, Second Paragraph

The Examiner maintained the rejection of Claims 1, 9 and 10 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner asserted that

The phrase "consisting essentially of" fails to contemplate the exclusion of any particular ingredients as implied therein and does not provide any criteria for determining if a given ingredient "materially affects the basic or novel characteristics of the invention". Therefore the phrase renders the claim indefinite.

(Office Action mailed August 31, 2009, pages 3 and 4.) Applicants respectfully traverse this rejection.

"In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim appraises one of ordinary skill in the art of its scope" (See MPEP § 2173.02.) "Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite." *Metabolite Labs., Inc., v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004).

The phrase "consisting essentially of" is well-known and understood. Present claims 1, 9 and 10 clearly apprise one of ordinary skill in the art of its scope, because one of ordinary skill in the art would know that the claim language, *i.e.*, "consisting essentially of," defines the claimed synergistic fungicidal composition to exclude a further active compound. In addition, at the time the present application was filed, one of ordinary skill in the art would know whether a given ingredient in a fungicidal composition is an active compound or a formulation aid, *e.g.*, extenders or surfactants. Therefore, present claims 1, 9 and 10 are clear and definite.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

IV. Rejection under 35 U.S.C. § 103(a)

Claims 1, 9 and 10 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Dutzmann *et al.* (US Patent No. 6,306,850) ("Dutzmann"). Applicants respectfully traverse this rejection.

A. *Prima Facie Case of Obviousness Has Not Been Established*

Applicants reiterate that for the reasons detailed in Applicants' Amendment and Reply of November 18, 2009, claims 1, 9 and 10 are not *prima facie* obvious over Dutzmann.

In sum, Dutzmann generally discloses a fungicidal composition comprising prothioconazole and one or more active compounds selected from 24 groups of listed active compounds, including tebuconazole and fluoxastrobin. Dutzmann does not disclose a specific three-compound composition containing fluoxastrobin, prothioconazole and tebuconazole, which possesses a synergistic fungicidal effect. As the Examiner acknowledged in the Office Action mailed on March 3, 2009, "the reference [Dutzmann] does not provide any motivation to select the specific combination of the active compounds of formulas (I), (III) and (XIV)."¹ (Office Action, mailed on March 3, 2009, at page 4). Consistent with the March 3, 2009, Office Action, in the April 7, 2010, Office Action the Examiner reiterated her construction of Dutzmann, without reasoned explanation, to suggest that one of ordinary skill in the art would combine fluoxastrobin and tebuconazole in a range "of 0.1:0.1 to 50:20." However, Dutzmann is silent regarding the ratio of fluoxastrobin to tebuconazole as required by each of present claims 1, 9 and 10.

Dutzmann discloses the ratio of *prothioconazole* to *fluoxastrobin* being from 1:0.1 to 1:50 (*see* Dutzmann, col. 12, line 22), or *fluoxastrobin* to *prothioconazole* being

¹ Dutzmann's active compounds of formulas (I), (III) and (XIV) correspond to Applicants' active compounds of formulas (II), (III) and (I).

"from 0.1:1 to 50:1" as characterized by the Examiner. (Office Action, page 5.) Dutzmann also discloses the ratio of *prothioconazole* to *tebuconazole* being from 1:0.1 to 1:20 (*see* Dutzmann, col. 11, line 63.) Dutzmann does not disclose the ratio of *fluoxastrobin* to *tebuconazole*. The Examiner has again asserted that Dutzmann "lead[s] one of ordinary skill in the art to the ratio" of fluoxastrobin to tebuconazole" being "from 0.1:0.1 to 50:20" (*see* Office Action, page 5). This unexplained conclusion appears to be derived from Dutzmann's disclosure of *prothioconazole* to *fluoxastrobin* from 1:0.1 to 1:50, and *prothioconazole* to *tebuconazole* from 1:0.1 to 1:20. The Examiner's conclusion is not supported by Dutzmann and the Examiner's explanation is not reasoned and/or disclosed. As discussed *supra*, Dutzmann generally discloses a fungicidal composition comprising prothioconazole as the principle fungicide, with one or more active compounds mixing partners, including fluoxastrobin and tebuconazole. Thus, Dutzmann discloses the mixing ratio of prothioconazole to its mixing partners, *e.g.*, prothioconazole to fluoxastrobin, and prothioconazole to tebuconazole. The ratio of fluoxastrobin to tebuconazole, the two mixing partners of prothioconazole, is not the subject matter of Dutzmann. A person of ordinary skill in the art would not have read Dutzmann as disclosing the ratio of fluoxastrobin to tebuconazole as asserted by the Examiner.

B. Synergistic Effects Rebut Any Prima Facie Case of Obviousness

Applicants reiterate that for the reasons detailed in Applicants' Amendments and Replies of June 3, 2009 and November 18, 2009, even assuming that a *prima facie* case of obviousness was established, the synergistic effect exhibited by the claimed combination is sufficient to overcome a *prima facie* case.

With respect to Applicant's Amendment and Reply of November 18, 2009, the Examiner states:

Examiner notes the typographical errors in the Dutzmann patent; however, applicant's claim to unexpected results does not appear to be supported. As Applicant disclosed, Table 7 did not give 100% efficacy for prothioconazole alone; however, when looking to International Publication, WO 98/47367 (as disclosed by applicant) at p. 51, Table 7, the ratio of prothioconazole to fluoxastrobin is 1:3 and the efficacy of the combination is 100%. Adding a third composition could not give anymore than the 100% received. As previously asserted, comparing the results in the Table on page 9 of the instant specification to the results in Table 5, column 37 of Dutzmann, the results for Dutzmann of the combination of prothioconazole and tebuconazole at a ratio of 1:1 and 1:3 resulted in an efficacy of 100%, furthermore adding a third composition could not give anymore than the 100% received, therefore there appears to be no support for synergism or unexpected results.

(Office Action mailed April 7, 2010, page 5.) Applicants respectfully disagree. The Examiner drew incorrect conclusions based on the totality of the data provided in Dutzmann. Taken as a whole, the disclosures and data of Dutzmann support the patentability of the invention.

Table 7 of WO 98/47367 ("Dutzmann-2," page 49) discloses a protective test of prothioconazole and fluoxastrobin against *Leptosphaeria nodorum* in wheat. As the Examiner acknowledged, Table 7 of Dutzmann-2 correctly discloses the results of testing prothioconazole, fluoxastrobin, and in combination as listed in Table A, below.

Table A: From Table 7 of Dutzmann-2 (*Leptosphaeria nodorum* Preventive Test)

Active Compound	Application Rate in g/ha	Efficacy (%)
Prothioconazole	25	62
Fluoxastrobin	25	87
Prothioconazole + Fluoxastrobin	6.25 + 18.75	100

Table 5 of Dutzmann-2 discloses a curative test of prothioconazole and tebuconazole against *Erysiphe graminis* f.sp. *tritici*, reporting, *inter alia*, the results of testing prothioconazole alone, tebuconazole alone, and in combinations, as listed in Table B, below.

Table B: From Table 5 of Dutzmann-2: *Erysiphe graminis* (Curative Test)

Active Compound	Application Rate in g/ha	Efficacy (%)
Prothioconazole	25	75
Prothioconazole	12.5	50
Prothioconazole	6.25	25
Tebuconazole	25	88
Prothioconazole + Tebuconazole	12.5 + 12.5	100
Prothioconazole + Tebuconazole	6.25 + 18.75	100
Prothioconazole + Tebuconazole	18.75 + 6.25	100

With respect to the data in Tables A and B, the Examiner stated that "adding a third composition could not give anymore than the 100% received." However, it was error for the Examiner to then assert that unexpected results could not have been obtained for the present ternary mixture because two sets of 100% efficacy results were disclosed in Dutzmann. If anything, the Examiner's analysis, i.e., that adding a third

composition could not give anymore than the 100% received, supports the patentability of the claimed invention. According to the logic of the Examiner, there would be no reason to add a third composition to the binary composition of Dutzmann. Under *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), there would have been no reason to add the third composition and the claims must not be obvious.

Moreover, the application rates of tebuconazole in the Dahmen Declaration (5 g/ha; 10 g/ha) were significantly reduced compared to the rates used in Dutzmann's binary compositions for preventive tests. (See Table B: 12.5, 6.25 and 18.75 g/ha). It would certainly be expected that lower application rates would result in lower efficacy. Thus, the results in the Dahmen Declaration are not inconsistent with the results disclosed in Dutzmann and must be considered when determining whether the claimed invention would have been obvious to one of ordinary skill in the art. In another example, on page 3 of the Dahmen Declaration, tebuconazole was shown to be completely ineffective at a treatment level of 5 g/ha on *Leptosphaeria nodorum* in a preventive test. The mixture of fluoxastrobin (37.5 g/ha), prothioconazole (37.5 g/ha) and tebuconazole (5 g/ha) unexpectedly gave 100% protection in comparison with the results predicted by the Colby formula (57%). This is to be compared with the protection reported by Dutzmann at much higher levels of tebuconazole. (For example, see Table B above: 25 g/ha of tebuconazole alone provided 88% efficacy against *Erysiphe graminis*). The binary compositions of Dutzmann in a similar *Erysiphe* test (Table C, below) did not provide 100% control of this fungus at low application rates of tebuconazole. Lowering the application rate of tebuconazole in the present ternary mixture and concomitantly raising its efficacy evidences the superiority of the ternary

mixture compared to at least some of the binary compositions of Dutzmann in preventive tests.

Table C: From Table 6 of Dutzmann: (*Erysiphe graminis* Preventive Test)

Active Compound	Application Rate in g/ha	Efficacy (%)
Prothioconazole	6.25	57
Tebuconazole	6.25	57
Prothioconazole + Tebuconazole	3.125 + 3.125	79
Prothioconazole + Tebuconazole	1.5625 + 4.6875	71
Prothioconazole + Tebuconazole	4.6875 + 1.5625	71

The Dahmen Declaration (pages 4-5) also provides the unexpected results of the present ternary combination against *Fusarium graminearum* in barley as a preventive treatment compared to each possible binary mixture.

The data of the present specification also shows unexpected results. The claimed composition exhibited an enhanced synergistic effect against *Erysiphe graminis* f.sp. *tritici* on wheat plants in a protective test, as compared to each possible binary mixture. The claimed synergistic ternary composition provided 100% control of *Erysiphe graminis* compared to 31% predicted by the Colby formula.

Finally, the Examiner said:

As previously asserted, assuming, purely *arguendo*, that unexpected results had been shown, Applicant's claims encompass a broader range than shown in the Table on p. 9 of the instant specification and Tables 1 and 2 of the declaration filed June 3, 2009, therefore the examples are not commensurate in scope with the instant claims.

(Office Action, page 6.) Applicants respectfully disagree.

As previously discussed, Applicants have demonstrated synergistic results of the presently claimed compositions at different mixing ratios and in controlling different fungi. Such synergistic results at least commensurate in scope with present claims 9 and 10.

For the reasons set forth above, Applicants respectfully request that the Examiner reconsider the evidence of unexpected synergistic effects presented in the specification and the Dahmen Declaration and that the rejection be withdrawn. The claimed composition is not obvious over Dutzmann.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

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1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
1135705_1.DOC